

**Remarks**

After entry of the amendment, claims 13-19 are pending.

The specification has been amended as requested by the Examiner in the Office Action. The specification has also been amended to identify other applications/patents to which the present application is related

Claims 8-12 have been canceled without prejudice.

Claims 13-19 are supported by the original claims and the specification at, for example, page 2, lines 1-3; page 18, lines 4-7; page 55, line 18 to page 57, line 15; and page 59, lines 22-29.

No issues of new matter should arise and entry of the amendment is respectfully requested.

**Rejections under 35 U.S.C. § 112**

Applicants respectfully submit that the new claims render the rejections under 35 U.S.C. § 112 moot, and respectfully request that the rejections under this provision be withdrawn.

**Rejection under 35 USC § 102(a)**

Applicants respectfully traverse the rejection and respectfully submit that US Patent No. 6,306,841 to Place et al (hereafter "Place") is not prior art to the present claims because Applicants can swear behind this reference.

As the Examiner is aware, the present application claims priority to October 31, 1997, while the filing date of Place is October 28, 1997. Accordingly, the present application has an effective filing date that is just 3 days after the filing date of Place (assuming, *arguendo*, that the claims in Place are entitled to the filing date of October 28, 1997).<sup>1</sup>

To swear behind Place, Applicants are submitting herewith a Declaration under 37 CFR § 1.131 by David S. Garvey, Ph.D. (the Garvey Declaration) and a Declaration under 37 CFR § 1.131 by S. William Tam, Ph.D. (the Tam Declaration) to establish that Applicants were in possession of the claimed invention prior to October 28, 1997.

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<sup>1</sup> Applicants reserve the right to challenge the current assumption that the claims in Place are entitled to the filing date of October 28, 1997.

Exhibit A of the Garvey Declaration is a document entitled "NitroMed Memorandum" dated October 29, 1997 (hereafter "the memorandum")<sup>2</sup> which states:

Enclosed are floppy disk and paper copies of the updated version of this application. ...I think you will find it is suitable for filing as is.

Dr. Garvey states that the floppy disk and paper copies of the application identified in the memorandum dated October 29, 1997, were the same as the application that was filed on October 31, 1997, as PCT/US97/19870, to which the present application claims priority.<sup>3</sup> As the Examiner can see, the specification of the present application is the same as the specification of PCT/US97/19870.<sup>4</sup>

Dr. Garvey stated that the application identified in the memorandum dated October 29, 1997, was prepared prior to October 28, 1997;<sup>5</sup> and that the application that was prepared prior to October 28, 1997, contained the same or substantially the same information as the application identified in the memorandum dated October 29, 1997, and the application filed October 31, 1997, as PCT/US97/19870.<sup>6</sup> Dr. Garvey further stated that – prior to October 28, 1997 – the application contained, *inter alia*, information that described methods of treating female sexual dysfunction by administering a pharmaceutical formulation comprising an S-nitrosothiol.<sup>7</sup>

The Garvey Declaration does not include a copy of the draft application that had been prepared prior to October 28, 1997, or a copy of the draft application identified in the memorandum of October 29, 1997, because it was NitroMed's company policy not to save any draft patent applications.<sup>8</sup>

Dr. Garvey's testimony is corroborated by his colleague, Dr. Tam, in the Tam Declaration. Drs. Garvey and Tam have been working together at NitroMed, Inc. since 1994.<sup>9</sup> Drs. Garvey and Tam generally had conversations about the research NitroMed was conducting in the

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<sup>2</sup> The Garvey Declaration at ¶ 4.

<sup>3</sup> Id. at ¶ 5.

<sup>4</sup> Id. at ¶ 5.

<sup>5</sup> Id. at ¶ 6.

<sup>6</sup> Id. at ¶ 7.

<sup>7</sup> Id. at ¶ 8.

<sup>8</sup> Id. at ¶ 9.

<sup>9</sup> The Garvey Declaration at ¶ 10; the Tam Declaration at ¶ 2.

chemical and biological areas and the subject matter in the patent applications that NitroMed was filing.<sup>10</sup>

Dr. Tam has corroborated Dr. Garvey's testimony that Dr. Garvey verbally conveyed to Dr. Tam that the application Dr. Garvey was preparing prior to October 28, 1997, described methods for treating female sexual dysfunctions using pharmaceutical formulations comprising S-nitrosothiols.<sup>11</sup>

Applicants respectfully submit that the Garvey and Tam Declarations demonstrate that the Applicants had possession of the claimed invention in the form of a draft patent application prior to October 28, 1997. The Applicants have established that they are properly entitled to swear behind Place pursuant to MPEP § 715.17, which provides that priority of invention may be established by any satisfactory evidence of the facts, including supporting statements by witnesses where verbal disclosures are the evidence relied upon. In addition to being supported by the MPEP, the Applicants evidence is sufficient to properly swear behind Place in view of the holding, for example, in *Ex parte Ovshinsky*, 10 USPQ2d 1075 (Bd. Pat. App. & Inter. 1989).

Applicants respectfully submit that the documentary evidence of October 29, 1997 (which shows that the Applicants had the application which described, *inter alia*, methods of treating female sexual dysfunctions with pharmaceutical formulations comprising S-nitrosothiols) is clearly supported by (1) the testimony of Dr. Garvey who stated that he had prepared a draft of the application prior to October 28, 1997, and that the draft application was substantially the same as the application that was filed on October 31, 1997, and (2) the corroborating testimony of Drs. Garvey and Tam who stated that Dr. Garvey verbally conveyed a description of the draft patent application (i.e., methods of treating female sexual dysfunctions using pharmaceutical formulations comprising S-nitrosothiols) to Dr. Tam prior to October 28, 1997.

In view of the above, Applicants respectfully submit that the Applicants have successfully sworn behind Place, and respectfully request that the rejection under 35 U.S.C. § 102(a) be withdrawn.

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<sup>10</sup> Id.

<sup>11</sup> The Garvey Declaration at ¶ 11; the Tam Declaration at ¶ 3.

**No Interfering Subject Matter**

In view of the newly submitted claim, Applicants respectfully submit that there is no interfering subject matter between the present claims and the claims in US Patent Nos. 6,306,841, 6,165,975 and 6,031,002 because the claims in the present application and the claims in these patents are separately patentable. MPEP § 2300.

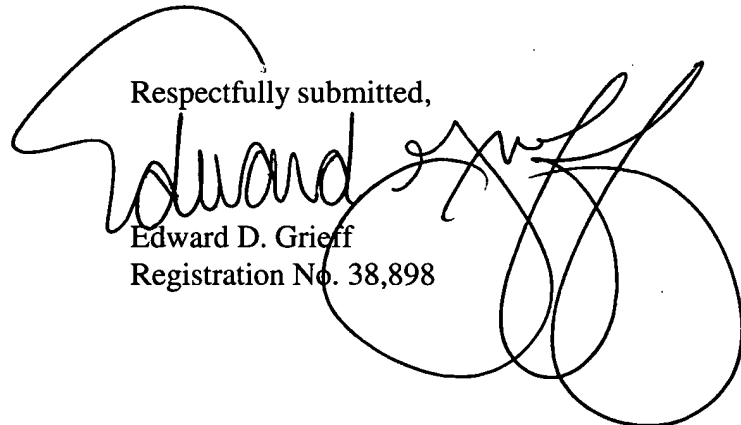
**Information Disclosure Statement**

Applicants are submitting an Information Disclosure Statement (IDS) herewith. Applicants respectfully request that the Examiner consider the references in the IDS and return an initialed copy of the PTO-1449 Form with the next communication from the Office.

**Conclusion**

An early and favorable reconsideration and allowance of claims 13-19 is respectfully requested. The Examiner is encouraged to contact the undersigned to expedite prosecution of this application.

Respectfully submitted,

A large, stylized handwritten signature in black ink, appearing to read 'Edward D. Grieff', is written over the typed name and registration number.

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Date: January 26, 2004  
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